

**MISSISSIPPI STATE DEPARTMENT OF HEALTH
DIVISION OF HEALTH PLANNING AND RESOURCE DEVELOPMENT
NOVEMBER 2011**

**CON REVIEW: ESRD-NIS-0911-019
FRESENIUS MEDICAL CARE – NORTH AMERICA, INC D/B/A RCG-WEST POINT
ESTABLISHMENT OF SATELLITE ESRD FACILITY
CAPITAL EXPENDITURE: \$808,367
LOCATION: WEST POINT, CLAY COUNTY, MISSISSIPPI**

STAFF ANALYSIS

I. PROJECT SUMMARY

A. Applicant Information

Fresenius Medical Care – North America, Inc. (applicant's legal name); Bio-Medical Applications of Mississippi, Incorporated (BMA of MS, Inc.), d/b/a RCG-West Point is a business corporation. The applicant indicates that BMA of MS, Inc. is governed by 2 directors and 14 officers. The applicant further states that Fresenius Medical Care Holdings, Inc., d/b/a Fresenius Medical Care of North America, the applicant's parent organization ("Fresenius") is a seven-member Board of Directors and has eight officers.

The applicant provided a Certificate from the Secretary of State dated February 28, 2011, verifying that the corporation was issued a Charter/Certificate of Authority on August 2, 1990. The document indicates that the business is incorporated in the State of Delaware; however, it is authorized by the Secretary of State to do business in Mississippi.

B. Project Description

Fresenius Medical Care – North America Inc., d/b/a RCG-West Point requests Certificate of Need (CON) authority to establish a ten (10 station), satellite End Stage Renal Disease ("ESRD") facility in Clay County.

The applicant intends to lease 5,809 square feet of shelled space and renovate the space to house the ten-station ESRD facility. The applicant states the proposed project includes: interior studs; dry wall; floor, wall and ceiling finishes; interior doors; specialty items; casework; complete plumbing; HVAC and electrical systems.

The applicant states that the proposed ten-station ESRD facility will be relocated from RCG-Tupelo, LLC d/b/a RCG-Aberdeen (RCG-Aberdeen) an affiliated ESRD facility. RCG-Aberdeen is located at 308 Hwy 8 West, Aberdeen, Mississippi. The applicant asserts that the proposed satellite ESRD facility will be located within 25 miles of RCG-Aberdeen.

The applicant states that currently there are no ESRD facilities located in Clay County. The applicant affirms that currently ESRD patients from West Point are traveling to Aberdeen, Columbus, and Starkville, Mississippi to receive dialysis care. The applicant states that there are three ESRD facilities located near the

proposed site: RCG of Starkville - approximately 18.09 miles, RCG of Columbus - approximately 18.72 miles, and RCG of Aberdeen which is located approximately 25 miles from the proposed site. The application contained letters of support from the ESRD facilities stated above.

The applicant believes that the establishment of a satellite facility in West Point, Mississippi will provide residents in Clay County a more convenient, accessible ESRD facility to receive dialysis services.

The MSDH Division of Health Facilities Licensure and Certification has approved the site for the proposed project.

The applicant expects to employ 10.9 full-time equivalent employees at a total personnel cost of \$463,494 during the first year of operation.

The total proposed capital expenditure for this project is \$808,367 that the applicant proposes to finance with cash reserves. The applicant anticipates that the capital expenditure will be obligated within one month of shell completion and total project completion within six months of start date.

II. TYPE OF REVIEW REQUIRED

This project for the establishment of an end stage renal disease facility is reviewed in accordance with Section 41-7-191, subparagraph (1)(a), of the Mississippi Code 1972, Annotated, as amended, and duly adopted rules, procedures, plans, criteria, and standards of the Mississippi State Department of Health.

In accordance with Section 41-7-197 (2) of the Mississippi Code of 1972 Annotated, as amended, any affected person may request a public hearing on this project within 20 days of the publication of the staff analysis. The opportunity to request a hearing expires on December 5, 2011.

III. CONFORMANCE WITH THE STATE HEALTH PLAN AND OTHER ADOPTED CRITERIA AND STANDARDS

A. State Health Plan (SHP)

The *FY 2012 State Health Plan* contains policy statements and service specific criteria and standards which the applicant is required to meet before receiving CON authority to establish a ten-station satellite ESRD facility. This application is in substantial compliance with applicable criteria and standards.

Policy Statement No. 14 of the 2012 State Health Plan states "Any existing ESRD facility which reaches a total of 30 ESRD stations, may establish a ten (10) station satellite facility. If a proposed satellite ESRD facility is to be located more than one (1) mile from the existing facility, a certificate of need must be obtained by the facility prior to the establishment of the satellite facility".

According to the *FY 2012 State Health Plan* RCG-Aberdeen has 32 certified and CON approved stations. The applicant states that the proposed facility will be located more than one mile from the existing Aberdeen facility. Therefore, the applicant is requesting CON approval for the establishment of a ten (10) station satellite ESRD facility in Clay County.

SHP Criterion 3- Need

Need Criterion for Establishment of ESRD Satellite Facilities: In order for a 30 station ESRD facility to be approved for the establishment of a ten (10) station satellite facility through the transfer and relocation of existing stations within a three mile radius or less from the existing facility, the facility must (a) document that it has maintained a minimum annual utilization rate of 65% for the 12 months prior to the month of the submission of the CON application; (b) justify the need for the project, which may include, but is not limited to, physical or space limitations at the existing facility; and (c) document that it is more cost effective to establish a satellite facility than to expand the existing facility. If the proposed satellite facility will be established at a location between a three and twenty-five mile radius of the existing facility, the facility must (a) document that it has maintained a minimum annual utilization rate of 65% for the 12 months prior to the month of the submission of the CON application; (b) justify the need for the project, which may include, but is not limited to, physical or space limitations at the existing facility; and (c) document that it is more cost effective to establish a satellite facility than to expand the existing facility; and (d) demonstrate that the proposed satellite facility's location is not within 30 miles of an existing facility without obtaining the existing facility's written support. NOTE: ESRD Policy Statements 2, 4, 5 and 6, and Need Criterion 1, do not apply to applications for the establishment of satellite ESRD facilities. An ESRD satellite facility established under this Need Criterion 3 shall not be used or considered for purposes of establishing or determining an ESRD Facility Service Area.

(a) Document that it has maintained a minimum annual utilization rate of 65% for the 12 months prior to the month of the submission of the CON application.

The applicant indicates that RCG-Aberdeen is currently experiencing 66.5% utilization on its 32 stations.

(b) Justify the need for the project, which may include, but is not limited to, physical or space limitations at the existing facility.

The applicant states that currently there are no ESRD facilities in Clay County. The applicant suggests that currently ESRD patients from West Point are traveling to Aberdeen, Columbus, and Starkville, Mississippi. The applicant believes that the further expansion of the Aberdeen facility is not as cost effective as establishing a satellite facility in West Point due to Life Safety Code requirements at the existing Aberdeen facility. Furthermore, the applicant states that the expansion at Aberdeen would still result in patients driving from West Point for required dialysis. The applicant considered expanding the Columbus facility and creating the West Point satellite from Columbus; however, due to the number of anticipated patient transfers from facilities to the satellite West Point location, the applicant believed relocating stations from Aberdeen would help relieve capacity issues at Columbus. If Columbus was expanded and stations relocated from Columbus, the drop in stations would further impact capacity issues. The applicant states that the relocation of stations from Aberdeen and anticipated patient transfers will increase the number of day chairs throughout the Golden Triangle area. Therefore, the applicant believes that the establishment of the satellite facility will best meet the needs of the current and future patients in the most cost effective manner.

(c) Document that it is more cost effective to establish a satellite facility than to expand the existing facility.

The applicant affirms that if Fresenius undertakes expansion at the Aberdeen facility, the entire cost for renovation in addition to the cost for space to house the new stations amount to a total construction cost of \$740,700. The applicant suggests that based on comparison of the two estimates the ten-station satellite facility at West Point (total construction cost of \$616,916) is more cost efficient. The applicant states that in addition to the cost savings, the proposed project will improve access for dialysis patients.

(d) Demonstrate that the proposed satellite facility's location is not within thirty miles of an existing facility without obtaining the existing facility's written support.

The application contained letters of support from RCG-Eupora, RCG-Columbus, and RCG-Starkville which are all located less than 30 miles from the proposed site. The applicant states that the proposed satellite facility will be located approximately 25 miles from the existing Aberdeen facility.

SHP Criterion 4 - Number of Stations

The applicant states that the satellite ESRD facility will contain ten hemodialysis stations in Clay County. Therefore, the applicant is in compliance with this criterion.

SHP Criterion 5 - Minimum Utilization

Network 8 data demonstrated an incidence rate of 11 from 2008 until 2010. Network 8 data also demonstrated that the prevalence of ESRD patients decreased in Clay County from 54 in 2008 to 53 in 2009, and 46 in 2010. The applicant projects 45 patients in year 1, 50 patients in year 2, and 55 patients in year 3 for the proposed ten-station satellite ESRD facility. Typically, an ESRD patient receives three treatments per week or 156 treatments per year. The following table compares the applicant's projections with the Department's requirements:

Year	Stations	Applicant's Projections			MSDH Requirements	
		Patients	Treatments	Utilization Rate	Treatments	Utilization Rate
1	10	45	6,120	65.4%	4,680	50%
2	10	50	6,840	73.1%	6,084	65%
3	10	55	7,560	80.7%	7,020	75%

SHP Criterion 6 - Minimum Services

RCG-West Point affirms that the facility will provide social, dietetic, and rehabilitative services.

SHP Criterion 7 - Access to Needed Services

RCG-West Point affirms that the applicant will provide reasonable access to equipment/facilities for such needs as vascular access and transfusions required by stable maintenance ESRD patients.

SHP Criterion 8 - Hours of Operation

RCG-West Point will operate between the hours of 7:00 a.m. to 6:00 p.m. six days a week. The applicant affirms alternate arrangements will be made for those patients needing after-hours treatments.

SHP Criterion 9 - Home Training Program

RCG-West Point affirms that patients who would like to participate in the home training program will be counseled on the availability of the home-training program and the requirements to enter the home/self-dialysis program. The Home Training program will be coordinated through the Home Therapies Department located in Columbus and Tupelo, Mississippi. The applicant provided letters evidencing Columbus' and Tupelo's agreement to provide back-up home dialysis services.

SHP Criterion 10 - Indigent/Charity Care

The applicant affirms that they will provide a reasonable amount of indigent/charity care and serve approximately 2% indigent/charity care patients. The applicant states it will serve all ESRD patients including Medicaid and Medicare recipients.

SHP Criterion 11 - Facility Staffing

The applicant included a proposed list of staff by category, position qualification guidelines (minimum education and experience requirements), and specific duties. If the proposed project is CON approved, the applicant affirms that 10.9 full time equivalents will be utilized to operate the satellite ESRD facility.

SHP Criterion 12 - Staffing Qualifications

The applicant asserts that the staff of the facility will meet, at a minimum, all requirements and qualifications as stated in the Medicare Conditions for Coverage of Suppliers of ESRD Services.

SHP Criterion 13 - Staffing Time

The applicant affirms that when the unit is in operation, at least one (1) R.N. will be on duty and at least two (2) persons will be present for each dialysis shift, one of which will be an R.N. In addition, the applicant affirms that the medical director or a designated physician will be on site or on call at all times when the unit is in operation. When the ESRD facility is not in operation, the applicant states that the medical director or a designated physician and one R.N. will be on call.

SHP Criterion 14 - Data Collection

The applicant affirms that it shall record and maintain the required data and shall make it available to the Mississippi State Department of Health as required by the Department.

SHP Criterion 15 - Staff Training

The applicant asserts that it will provide an ongoing training program for nurses and technicians in dialysis techniques at the facility.

SHP Criterion 16 -Scope of Privileges

The applicant affirms that it will provide access to doctors of medicine or osteopathic medicine licensed by the State of Mississippi who possess qualifications established by the proposed governing body of the facility. The applicant states that their affiliated facilities within the service area, has existing relationships with nephrologists in the area who currently treat the applicant's patients and will continue to treat the patients at the proposed facility.

SHP Criterion 17 - Affiliation with a Renal Transplant Center

The applicant affirms that they will enter into an affiliation agreement with a transplant center within one (1) year after the facility is opened and operating. The applicant provides a copy of the transfer agreement with the University of Mississippi Medical Center and the University of Alabama. The applicant anticipates this same agreement or a similar agreement will be applicable to the proposed facility.

B. General Review (GR) Criteria

Chapter 8 of the *Mississippi Certificate of Need Review Manual, May 1, 2010, Revision*, addresses general criteria by which all CON applications are reviewed. This application is in substantial compliance with general review criteria.

GR Criterion 1 – State Health Plan

This application is in compliance with the overall objectives of the *FY 2012 State Health Plan*.

GR Criterion 2 – Long Range Plan

The applicant's long range plan is to provide high quality, easy to access ESRD services for those residents in need of dialysis services in Clay County. The applicant believes the proposed facility will help relieve the patient load at other Golden Triangle area affiliated facilities and the smaller facility will offer a calmer environment.

GR Criterion 3 – Availability of Alternatives

The applicant considered the following alternatives:

- Not establishing a satellite ESRD facility in West Point and continuing to service those patients through its existing facilities – the applicant stated that given the growth of ESRD patients in the Golden Triangle area, the option wasn't feasible.
- Expansion of the Aberdeen facility - the applicant found it is not as cost effective as establishing a satellite facility in West Point due to Life Safety Code requirements at the existing Aberdeen facility. Furthermore,

the applicant states that the expansion at Aberdeen would still result in patients driving from West Point for required dialysis.

- Expanding the Columbus facility and creating the West Point satellite from Columbus - however, due to the number of anticipated patient transfers from facilities to the satellite West Point location, the applicant believed relocating stations from Aberdeen would help relieve capacity issues at Columbus. If Columbus was expanded and stations were relocated from Columbus, the drop in stations would further impact capacity issues.

The applicant suggests that the relocation of stations from Aberdeen and anticipated patient transfers will increase the number of day chairs throughout the Golden Triangle area. The applicant further states that the establishment of a satellite facility will also decrease travel time for patients to receive dialysis.

The applicant believes that the establishment of a ten-station satellite ESRD facility in West Point will be the most efficient, effective, and accessible alternative to meet the needs of the patients in the Golden Triangle area.

GR Criterion 4 – Economic Viability

Based on the applicant's three-year projections, this project will have a net income of \$186,021 the first year, \$231,262 the second year, and \$275,407 the third year of operation, respectively.

The applicant submits that the ESRD reimbursement environment and the patient population of the area are ever changing; however, the applicant has the financial strength to operate the facility at a loss, if necessary.

- a. **Proposed Charge:** The applicant submits that the proposed project will not increase the cost of dialysis services to patients or Medicaid. The applicant believes that the experience gained by Fresenius in effectively operating other ESRD facilities in the service area and across the state will help ensure that there will not be a negative effect on the cost of health care as it is associated with the project. The applicant also believes that the charge for the services is comparable to other ESRD facilities' charges because Medicare sets in advance a composite rate per treatment for each geographic area.
- b. **Projected Levels of Utilization:** The applicant makes the following projections of dialysis treatments to be performed during the first three years of operation: 65.4%; 73.1%; and 80.7% respectively.

GR Criterion 5 – Need for Project

- a. **Access by Population Served:** The applicant states that currently there are no ESRD facilities in Clay County. The applicant affirms that currently ESRD patients from West Point are traveling to Aberdeen, Columbus, and Starkville, Mississippi to receive care. The applicant states that dialysis services will be offered to all ESRD patients, including without limitation, to the underserved population.

- b. Relocation of Services:** The applicant states that while ten stations from Aberdeen will be relocated to create the proposed satellite facility, services will continue to be provided at the existing location. Therefore, this application does not entail the relocation of services or replacement of an ESRD facility.
- c. Probable Effect on Existing Facilities in the Area:** As previously stated above, the applicant submitted that currently there are three ESRD facilities located near the proposed service area: RCG of Starkville - approximately 18.09 miles; RCG of Columbus - approximately 18.72 miles; and RCG of Aberdeen which is located approximately 25 miles from the proposed site. The application contained letters of support from the ESRD facilities stated above.
- d. Community Reaction:** The application contained nine letters of support for the proposed project.

GR Criterion 6 – Access to the Facility or Service

According to the applicant, all patients of the ESRD service area, including Medicaid recipients, charity/medically indigent patients, racial and ethnic minorities, women, handicapped persons, and the elderly, will have access to the services of the facility.

The following table shows the projected estimated gross patient revenues of health care provided to charity/medically indigent patients for years one and two for the proposed project:

Projected Year	Total Dollar Amount of Gross Patient Revenue
1	\$32,284.96(2%)
2	\$36,669.78(2%)

The proposed facility will operate Monday through Saturday from 7:00 a.m. to 6:00 p.m.

GR Criterion 7 – Information Requirement

The applicant affirms that it will record and maintain the requested information required by this criterion and make it available to the Mississippi State Department of Health within 15 days of request.

GR Criterion 8 – Relationship to Existing Health Care System

The applicant affirms that there are no ESRD facilities in Clay County. Currently residents travel to other counties in the Golden Triangle area to receive ESRD services. The applicant's related facilities are the only ESRD facilities within the Service Area. These facilities will in essence serve the same population and will cooperate to transfer any patients from the facility to the West Point facility for the patient's continuity of care.

The applicant believes that failure to implement this project will result in current and future ESRD patients residing near West Point, continuing to travel three

times a week to other locations in the Golden Triangle area to receive necessary dialysis services.

GR Criterion 9 – Availability of Resources

The applicant states that its affiliates have successfully recruited, through advertising and word-of-mouth, and maintained the personnel necessary for the efficient operation of their current facilities. The applicant proposes to use the same method. Furthermore, the applicant states, that in the event of a shortage of staff at the new facility, the affiliation with the next closest facility, will allow the applicant and the other facilities to supplement and share staff if ever necessary. The applicant affirms that due to its existing presence in the area, relationships with nearby nephrologists have been established.

GR Criterion 10– Relationship to Ancillary or Support Services

The applicant affirms that all necessary ancillary or support services will be available.

GR Criterion 11– Health Professional Training Programs

Fresenius Medical Care – North America Inc., d/b/a RCG-West Point asserts the facility will coordinate with area health professional schools to have access to the services for training purposes.

GR Criterion 16– Quality of Care

The applicant states that while this application does not concern an existing ESRD facility, their relationship with Fresenius will greatly benefit the proposed facility due to Fresenius’ integrated delivery and service model. The applicant suggests this affiliation will help guarantee quality of care through delivery of health services, staff training and expectations.

IV. FINANCIAL FEASIBILITY

A. Capital Expenditure Summary

Cost Item	Projected Cost	% of Total
Construction Cost - New	\$ 0	0.00%
Construction Cost - Renovation	522,810	64.67%
Capital Improvements	0	0.00%
Total Fixed Equip Cost	112,620	13.93%
Total Non-Fixed Equip Cost	78,831	9.75%
Land Cost	0	0.00%
Site Prep Cost	0	0.00%
Fees – architectural/engineering	41,825	5.17%
Fees - legal and accounting	0	0.00%
Contingency Reserve	52,281	6.47%
Capitalized Interest	0	0.00%
Total Proposed Expenditures	\$808,367	100.00%

B. Method of Financing

The applicant proposes that the project will be financed from cash reserves.

C. Effect on Operating Cost

Attachment 1 lists RCG-West Point's projections of expenses, revenues, and utilization for the first three years of operation.

D. Cost to Medicaid/Medicare

ESRD treatment is a Medicare entitlement. As such, the Medicare program will absorb a majority of the costs associated with this project. The cost to the Medicaid program will be negligible.

V. RECOMMENDATIONS OF OTHER AFFECTED AGENCIES

The Division of Medicaid was provided a copy of this application for review and comment; however, the department received no response, as of the date of this staff analysis.

VI. CONCLUSION AND RECOMMENDATION

This project is in substantial compliance with the criteria and standards for the establishment of an satellite ESRD facility as contained in the *FY 2012 State Health Plan*; the *Mississippi Certificate of Need Review Manual, Revised September 1, 2011*; and all adopted rules, procedures, and plans of the Mississippi State Department of Health.

Therefore, the Division of Health Planning and Resource Development recommends approval of the application submitted by Fresenius Medical Care – North America Inc., d/b/a RCG-West Point for the establishment of a ten (10 station), satellite End Stage Renal Disease ("ESRD") facility in Clay County.

Fresenius Medical Care – North America Inc.
d/b/a
RCG-West Point

Three-Year Operating Statement
Attachment I

	Year 1	Year 2	Year 3
Revenue			
Inpatient Care Revenue			
Outpatient Revenue	\$1,624,248	\$1,833,489	\$2,046,753
Gross Patient Revenue	\$1,624,248	\$1,833,489	\$2,046,753
Charity			
Deductions from Revenue			
Net Patient Care Revenue	\$1,624,248	\$1,833,489	\$2,046,753
Other Operating Revenue			
Total Operating Revenue	\$1,624,248	\$1,833,489	\$2,046,753
Operating Expenses			
Salaries	\$ 381,919	\$ 431,938	\$ 483,536
Benefits	81,575	91,623	103,280
Supplies	578,034	651,165	725,431
Services			
Lease Expenses	89,793	91,536	93,331
Depreciation	85,623	85,623	85,623
Interest			
Other	221,283	250,342	280,145
Total Operating Expenses	\$1,438,227	\$1,602,227	\$1,771,346
Net Operating Income	\$ 186,021	\$ 231,262	\$ 275,407
	Proposed	Proposed	Proposed
	Year 1	Year 2	Year 3
Outpatient visits	313	313	313
Number of Procedures	6,120	6,840	7,560
Charge per outpatient day	\$5,189	\$5,858	\$6,539
Charge per Procedure	\$ 265	\$ 268	\$ 271
Cost per outpatient day	\$4,595	\$5,119	\$5,659
Cost per Procedure	\$ 235	\$ 234	\$ 234